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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,022	01/29/2002	Frank Runge	52141	2669

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/058,022	RUNGE ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of Applicant's Response, Amendment and Arguments/Remarks, all filed 03/21/05 is acknowledged.

Claims 1-20 are pending. Claims 1-10 and 16-18 have been amended. Claims 1-20 remain rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 6, 7 and 9-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen *et al.* (WO 91/06292) in view of Horn *et al.* (US Pat. No. 4,522,743).

Jensen teaches a process for preparing powders comprising water dispersible hydrophobic or aerophilic powdered colorants – carotenoids, wherein the solids (carotenoids) are milled in an aqueous medium in the presence of a hydrocolloid to obtain a suspension containing suspended particles, finely dividing and drying the suspension to obtain a powder, whereby soybean protein is used as a suitable protective hydrocolloid and sucrose is contained in the aqueous medium (see reference pages 1, 4, 5, examples on pgs. 8-14 and abstract).

Solid hydrophobic/aerophilic materials that can be milled and encapsulated in the process are carotenoids, such as Beta-carotene, lutein, beta-apo-8'-carotenal, canthaxanthin, astaxanthin, citranaxanthin, derivatives thereof and the like (page 4, lines 25-33).

Hydrocolloids that can also be used include exudates, extracts from seaweed, extracts from plants, extracts from marine and terrestrial animals, such as gelatins and other proteinaceous hydrocolloids, flours from seeds, such as soya bean and proteins from seeds, such as soya bean protein, etc. (pg. 4, line 35 thru pg. 5, line 9).

The aqueous medium can further contain excipients in an amount of up to 70 percent by weight of the suspension, such as a dissolved carbohydrate, such as sorbitol and sucrose, and/or an antioxidant or oil containing an antioxidant. The resulting suspension is finely divided and dried using any combination of conventional methods, such as spray cooling, spray drying, modified spray drying or sheet drying, crushing, etc. (page 5, lines 19-26).

In the spray cooling, spray drying and modified spray drying processes, excipients that may be used are, for example, starches, modified starches, *lactose*, mannitol, ethyl cellulose, etc. (pg. 6, line 39 thru pg. 7, line 5).

Jensen states that the amounts of the hydrophobic/aerophilic solids (carotenoids) are used in an amount of up to 71% (pg. 3, lines 5-13). This amount meets the applicant's claimed range of from 0.1 to 30% by weight.

The carotenoid preparation may be used in pharmaceutical compositions, foods and feedstuffs (pg. 8, lines 1-7).

Example 1 demonstrates the teaching of a milled suspension using a carotenoid - Beta-carotene in a solution mixture with sucrose, ascorbyl palmitate and tocopherol (page 8). Example 6 provides canthaxanthin in a solution with sucrose having a temperature of 65°C.

Jensen's patent is lacking in the sense that he teaches sucrose, rather than lactose in a mixture with a hydrocolloid. However, lactose is a well-known protein stabilizer conventionally used by one skilled in the art. Such skill is also evident from the reference of Horn *et al.* (see below).

Horn *et al.* ('743) teach a process for preparing a finely divided pulverulent carotenoid composition wherein sugar or sugar alcohols, such as sucrose and lactose are advantageously added to the colloid in order to increase the mechanical stability of the end product (see reference col. 3, lines 27-39).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Horn within Jensen, because Horn explicitly teaches

that it is advantageous to add lactose or sucrose to a colloid, which functions to increase the mechanical stability of the end product and similarly Jensen teaches a process utilizing carotenoids in a mixture with sugars or sugar alcohols, such as sucrose. One skilled in the art would be further motivated to use either lactose or sucrose in admixture with a carotenoid, since they are functionally equivalent as taught by Horn. The expected result would be a mechanically stabilized carotenoid composition.

Claims 5, 8 and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen *et al.* (WO 91/06292) as applied to claims 1-4, 6, 7 and 9-15 above and further in view of Dobler *et al.* (WO 96/01570).

The teachings of Jensen have been discussed above.

Jensen does not teach a partially degraded soybean protein having a degree of hydrolysis of from 0.1 to 20%

Dobler teaches protective colloids for fat-soluble active substances (carotenoids), wherein the protective colloids are partially degraded soybean proteins having a degree of hydrolysis (degradation) of 0.1 to 5% (pg. 3, lines 4-8).

Therefore it would have been obvious to one of ordinary skill in the art to use the combined teachings of Dobler within Jensen because Dobler explicitly teaches a carotenoid composition containing partially degraded soybean proteins with a degree of hydrolysis of 0.1 to 5% (instant range recites 0.1 to 20%) and similarly Jensen teaches a cartenoid/hydrocolloid preparation and process for preparing whereby soybean protein is used as the suitable protective

hydrocolloid. The expected result would be an effective carotenoid formulation having improved stability.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dobler *et al.* (WO 96/01570) in view of Horn *et al.* (US Pat. No. 4,522,743).

Dobler teaches partially degraded soybean proteins as protective colloids for carotenoids wherein water-dispersible compositions are produced with soybean proteins and protective colloids in an aqueous medium and whereby glucose is contained in the aqueous medium to obtain a resulting dry powder (see reference pages 1-4 and examples).

According to Dobler, an objective of the invention is to find suitable protective colloids for fat-soluble active substances that do not involve technical disadvantages for processing and make it possible to produce in a simple way, stable, coldwater-dispersible compositions of fat-soluble active substances (carotenoids) (pg. 2, line 45 thru pg. 3, line 2).

Dobler teaches that the protective colloids for fat-soluble active substances (carotenoids) are partially degraded soybean proteins, which have a degree of hydrolysis (degradation) of 0.1 to 5% (pg. 3, lines 4-8).

The soybean proteins usually employed are commercial soybean protein isolates and concentrates with protein contents of from 70 to 90% by weight, where the remaining 10 to 30% by weight represent other undefined plant constituents. The soybean protein isolates are incubated with the enzyme in aqueous medium, preferably at from 50 to 70°C and at a pH of from 7 to 9. The suitable protein to enzyme ratio for the desired degree of degradation

(hydrolysis) can be determined by laboratory tests which are simple for the skilled worker (pg. 3, lines 24-32).

Suitable fat-soluble active substances are carotenoids, for example, Beta-carotene, apocarotenal, ethyl apocarotenoate, canthaxanthin, zeaxanthin, astaxanthin, lycopene, citranaxanthin or mixtures of said substances (pg. 3, lines 38-43).

The fat-soluble active substances can be added to the compositions either in pure form or as a mixture with physiologically tolerated oils (i.e., sesame oil, soybean oil, corn oil, etc.). In addition to the fat-soluble active substances and the partially degraded soybean proteins, the compositions may also contain conventional auxiliaries, for example, sugars and sugar alcohols, starch and derivatives, stabilizers and emulsifiers (pg. 4, lines 1-11).

The compositions can be either in liquid or solid form, however solid compositions are preferred. Spray drying or spray fluidized bed drying can be used to produce the solid compositions. The fat-soluble active substances are contained in amounts from 2 to 40% of the total weight of active substance and protective colloid (pg. 4, lines 21-29). This range meets the applicant's claimed amounts of 0.1 to 30% carotenoid content.

According to Dobler, the compositions are outstandingly suitable for use in livestock nutrition, as an additive to foodstuffs or as an addition to drinking water. Carotenoid-containing compositions are also suitable as foodstuff colorants, especially for soft drinks (pg. 4, lines 34-40).

The examples on pages 5-7 demonstrate a process for preparing dry powders comprising protective colloids - soybean proteins in a mixture solution with various carotenoids and glucose.

For instance, example 4 provides a dispersion of citranaxanthin with soybean protein isolate and glucose to obtain a dry powder containing 3.0% citranaxanthin content.

Although Dobler is lacking in the sense that he teaches glucose, rather than lactose in combination with soybean protein and carotenoids, one of ordinary skill in the art would be able to substitute glucose for lactose to obtain similar results. Such skill is also evident from the reference of Horn *et al.* (see below).

Horn *et al.* ('743) teach a process for preparing a finely divided pulverulent carotenoid composition wherein sugar or sugar alcohols, such as glucose and lactose are advantageously added to the colloid in order to increase the mechanical stability of the end product (see reference col. 3, lines 27-39).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Horn within Dobler, because Horn explicitly teaches that it is advantageous to add either lactose or glucose to a colloid, which functions to increase the mechanical stability of the end product and similarly Dobler teaches a process utilizing carotenoids in a mixture with sugars or sugar alcohols, such as glucose. One skilled in the art would be further motivated to use either lactose or glucose in admixture with carotenoids, since they would be functionally equivalent and provide a similar outcome, as taught by Horn. The expected result would be a mechanically stabilized carotenoid composition.

Prior art made of record, deemed relevant by Examiner:

- Auweter *et al.* US Pat. No. 6,296,877 B1 (10/2001)

Auweter *et al.* teach stable aqueous dispersions and stable water-dispersible dry powders comprising mixtures of protective colloids, whereby to increase mechanical stability of the end product, it is expedient to admix the colloid with sugars or sugar alcohols, eg. sucrose, glucose, lactose, invert sugar, etc. (see column 3, lines 42-45).

Response to Arguments

Applicant's arguments filed 03/21/05 have been fully considered, but they are not persuasive.

Applicant argued in regards to the following rejections:

- The 35 U.S.C. §103(a) rejection of claims 1-4, 6, 7 and 9-15 over Jensen et al. (WO '292) taken alone or in view of Horn et al. (US '743).
- The 35 U.S.C. §103(a) rejection of claims 5, 8 and 16-20 over Jensen et al. (WO '292) in view of Dobler (WO '570).
- The 35 U.S.C. 103(a) rejection of claims 1-20 over Dobler *et al.* (WO '570) in view of Horn *et al.* (US '743).

Applicant argued, "Neither one of the prior art references suggests or implies that dry powders exhibiting distinctly different properties are obtained depending upon whether: (a) a mixture comprising effective amounts of lactose and the at least one soy bean protein referenced in Applicant's claims or (b) a mixture comprising glucose and at least one soy bean protein, is

employed in the preparation of the dry powder, nor has the Examiner given any consideration to that fact. The prior art fails to suggest or imply that (a) the nature of the protective colloid and/or (b) the nature of the excipient or auxiliary have any significant impact on the quality of the dry powder obtained. The prior art does neither suggests nor implies that the nature of the protective colloid and/or the nature of the excipient or auxiliary are result effective parameters. Applicant's findings that particular results are obtained cannot be deemed as being based on routine optimization."

Applicant's arguments have been considered, but were not found persuasive. Applicants have now amended claims to recite a 'method of improving the apparent density and stability of a dry powder of one or more carotenoids'. This amendment has not overcome the art since the prior art teaches and recognizes formulations comprising the use of protective colloids in combination with sugars to obtain suitable dry powder formulations. While the primary references teach distinct sugars than that claimed (*i.e.*, sucrose/glucose as opposed to lactose), the secondary references remedy this deficiency by teaching that it is well known to employ lactose in colloidal preparations in order to increase the mechanical stability of the end product. Note in particular, col. 3, lines 35-39, whereby Horn *et al.* explicitly teach that 'to increase mechanical stability of the end product, it is advantageous to add to the colloid a plasticizer, such as sugar or sugar alcohol, eg. sucrose, glucose, lactose, invert sugar, etc'. According to this teaching, it is demonstrated that various sugars, including lactose is a well-known stabilizer conventionally used by one skilled in the art to increase mechanical stability, as demonstrated by Horn *et al.* One of ordinary skill in the art desiring to improve the overall stability of the end product would look to the teachings of Horn *et al.*, based on their teaching that lactose (as well as

glucose/sucrose) is a sugar that enables increase in stability. Therefore, Applicant's argument that the prior art does not recognize beneficial results or properties obtained through the use of the particular excipient or auxiliary are not persuasive since the prior art teachings clearly suggest the benefits of employing sugars or sugar alcohols to enhance colloidal formulations. The prior art incorporates similar ingredients, which clearly resolve issues of instability, as also desired by Applicants. Moreover, it is not necessary that the prior art teach each and every property that accrues from the use of a particular ingredient, merely that the prior art suggest that component in a related field of endeavor for a similar purpose is sufficient. In this instance, the prior art teaches suitable and effective processes for the preparation of dry carotenoid powders, utilizing protective colloids in combination with various sugars, lactose being one of the sugars, as instantly claimed. Therefore, since the prior art teaches the use of the same ingredients for the same field of endeavor and for the same intended purpose as that of Applicants, the instant invention is clearly rendered *prima facie* obvious over the cited art of record.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh H.N.S.

Patent Examiner

Art Unit 1615

June 02, 2005

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